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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,028	03/16/2000	Sylvie Veriac	0198/053	1839

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EXAMINER
GABEL, GAILENE

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/527,028	VERIAC ET AL.	
	Examin r	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 9/28/01 in Paper No. 4 is acknowledged and has been entered. Claims 1-11 have been cancelled. Claims 12-24 have been added. Accordingly, claims 12-24 are pending and under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

2. The rejections of claims 1-11 under 35 U.S.C. 112 and 103 are now moot in light of Applicant's cancellation of the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12, preamble, "basophile" should be "basophil". Further, "hemeglobin" should be "hemoglobin".

Claims 13-24 are objected upon for depending from a rejected claim (claim 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 12-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takarada et al. (US 5,677,183) in view of Hamaguchi et al. (US 5,389,549) and in further view of Uchihashi et al. (US 5,968,832).

Takarada et al. disclose a reagent system comprising a first and a second reagent for identifying and classifying leucocytes including basophil (see column 8,lines 37-56). Specifically, the first reagent comprises a cationic detergent such as quaternary ammonium salt, present in sufficient amount to lyse erythrocytes and damage or porify leucocyte cell membrane, i.e. 0.5 - 300 g/l. The first reagent further includes a buffer

such as phthalic acid or citric acid for adjusting pH to a desired pH of <3.0, preferably 2.0 and may further include alkali metal salts and inorganic salts such as sodium chloride and potassium chloride (see column 5, lines 9-24). The second reagent is used for measuring basophils which also includes a cationic detergent such as quaternary ammonium salt, a buffer for maintaining the pH at 2.5 - 4.0 such as phthalic acid or citric acid, a nonionic surfactant, and also alkali metal or inorganic salts.

Takarada et al. differ in failing to disclose a nitrogenous compound in the reagent system.

Hamaguchi et al. disclose a reagent for counting and classifying leucocytes including basophil and lysing erythrocytes. Specifically, the reagent comprises a blood diluent including a phosphate buffer, sodium chloride, and a hyperosmotic or cytolytic agent; an ionic detergent; an nonionic detergent; and a nitrogenous compound for use in reducing the sizes of monocytes in leucocytes. The nitrogenous compounds is thiourea or 1,3- dimethylurea. The reagent buffer maintains the pH at 1.5-5.0. Hamaguchi et al. disclose that the reagent is enabled for basophil measurement comprising a buffer having potassium phthalate, hydrochloric acid, nitric acid, and a lysing agent at an acidic pH of 3.0. Specifically, Hamaguchi et al. disclose that when a solubilizing agent is incorporated into a lysing agent or diluent, the solubilizing agent selectively promotes the action of the lysing reagent into monocytes. Hamaguchi et al. also specifically disclose that such selective action of solubilizing agents to monocytes is also effective with all other reagents used in leucocyte classification.

Takarada et al. and Hamaguchi et al. differ in failing to disclose the reagent capable of additionally measuring hemoglobin content.

Uchihashi et al. disclose a reagent for measurement of leucocytes and hemoglobin concentration including a cationic detergent and a hemoglobin stabilizer including sulfosalicylic acid, a chelating agent having a nitrogen compound, and a salt (see Abstract).

One of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success in incorporating the solubilizing agent / nitrogenous compound as taught by Hamaguchi and the hemoglobin reagent disclosed by Uchihashi into the reagent system taught by Takarada because Hamaguchi specifically disclosed and suggested conventional applicability of different such agents with all other reagents used in leucocyte classification such as the reagent system taught by Takarada.

Takarada et al., Hamaguchi et al., and Uchihashi et al. differ in failing to disclose the specific concentration parameters of elements recited in claims 23 and 24.

It is, however, maintained that the concentration parameters such as detergent [0.2-20 g/l] and nitrogenous compound [0.1-10 g/l] recited in claim 23 and potassium chloride [5-15 g/l], 1,3- dimethyl-2- thiourea [0.5-5 g/l], dodecyltrimethylammonium chloride [0.5-5 g/l], and potassium hydrogen phosphate / HCl [1.0-10 g/l] which are recited in claim 24, are all result effective variables which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a

claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims 23 and 24 are for any particular purpose or solve any stated problem and the prior art teaches that the different reagent elements and parameters often vary according to the sample being analyzed and parameters appear to work equally as well; absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the Takarada, Hamaguchi, and Uchihashi by normal optimization procedures known in the leucocyte differentiation art.

5. Claims 12-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakata et al. (US 5,538,893) in view of Hamaguchi et al. (US 5,389,549) and in further view of Uchihashi et al. (US 5,968,832)..

Sakata et al. disclose a reagent system for analyzing and classifying leucocytes including basophil which is capable of determining cell size and morphological features of leucocytes (see Abstract and column 2, lines 18-39). Specifically, the reagent comprises a nonionic detergent, a buffer for adjusting the pH to 2.5 - 4.0, and a cationic

detergent (surfactant) such as quaternary ammonium salt for complete lysis of erythrocytes and baring the nuclei of granulocytes other than basophil (see column 4, lines 21-59). The reagent buffer used includes citric acid and tartaric acid as well as alkali metal hydroxides such as sodium hydroxide and potassium hydroxide for adjusting pH to a desired pH of 2.0 - 5.0 (see column 5, lines 25-40). The surfactants and the buffer can be prepared and mixed at desired ratios (see column 5, lines 44-63). The reagent system may further contain alkali metal salts and inorganic salts such as sodium chloride and potassium chloride (see column 6, lines 1-6). Sakata et al. disclose that at appropriate concentrations, cell lysing is exhibited and lymphocytes and monocytes immature granulocytes and basophils which include a large percentage of basophilic granules are hardly shrunk allowing differentiation in sizes of leucocytes (see column 7, lines 36-47).

Sakata et al. differ in failing to disclose a nitrogenous compound in the reagent system.

Hamaguchi et al. has been discussed supra. Sakata et al. and Hamaguchi et al. differ in failing to disclose the reagent capable of additionally measuring hemoglobin content.

Uchihashi et al. disclose a reagent for measurement of leucocytes and hemoglobin concentration including a cationic detergent and a hemoglobin stabilizer including sulfosalicylic acid, a chelating agent having a nitrogen compound, and a salt (see Abstract).

One of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success in incorporating the solubilizing agent / nitrogenous compound as taught by Hamaguchi and the hemoglobin reagent disclosed by Uchihashi into the reagent system taught by Sakata et al. because Hamaguchi specifically disclosed and suggested conventional applicability of different such agents with all other reagents used in leucocyte classification such as the reagent system taught by Sakata.

Sakata et al., Hamaguchi et al., and Uchihashi et al. differ in failing to disclose the specific concentration parameters of elements recited in claims 23 and 24.

It is, however, maintained that the concentration parameters such as detergent [0.2-20 g/l] and nitrogenous compound [0.1-10 g/l] recited in claim 23 and potassium chloride [5-15 g/l], 1,3- dimethyl-2- thiourea [0.5-5 g/l], dodecyltrimethylammonium chloride [0.5-5 g/l], and potassium hydrogen phosphate / HCl [1.0-10 g/l] which are recited in claim 24, are all result effective variables which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276,

205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims 23 and 24 are for any particular purpose or solve any stated problem and the prior art teaches that the different reagent elements and parameters often vary according to the sample being analyzed and parameters appear to work equally as well; absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the Sakata, Hamaguchi, and Uchihashi by normal optimization procedures known in the leucocyte differentiation art.

6. No claims are allowed.

Response to Arguments

7. Applicant's arguments with respect to claims 12-24 have been considered but are moot in view of the new grounds of rejection.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
December 16, 2001

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12/17/01